

Multidisciplinary Treatment of Obesity with a Protein-sparing Modified Fast: Results in 668 Outpatients

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Abstract: Six hundred sixty-eight obese outpatients, 71 per cent (± 34) in excess of ideal weight, were enrolled in a multidisciplinary weight control program. The major components of the program included nutrition, education, behavior modification, and exercise. Rapid weight loss was accomplished using a very low calorie (less than 800 kcal) ketogenic diet. Patients adhered to the protein sparing modified fast (PSMF) for 17 ± 12 weeks and averaged 9 ± 17 weeks in a refeeding/maintenance program. Mean weight loss was 47 ± 29

lb (21 ± 13 kg) at the point of minimum weight and 41 ± 29 lb (19 ± 13 kg) at the end of the maintenance period. Systolic and diastolic blood pressure and serum triglycerides fell significantly in men and women. Success in weight loss was greatest in the heaviest patients, those who adhered the longest to the PSMF, and those who stayed the longest in the maintenance program. (*Am J Public Health* 1985; 75:1190-1194.)

Introduction

Despite the unfortunate experiences caused by widespread, unsupervised use of low-quality liquid protein diets in the early 1970s,¹ responsible versions of very low calorie diets (VLCDs) are now recognized as a safe and appropriate therapy for high-risk obesity.² Safe use of VLCDs requires protein sources of high biologic value and supplementation with proper vitamins, minerals, and electrolytes. These diets must be supervised by medical personnel familiar with the metabolism of fasting, and limited to patients with "medically significant obesity."³

The threshold for defining medically significant obesity has been cited by various authors as ranging from 120 per cent to 160 per cent of ideal body weight (relative weight).⁴⁻⁷ Since the risks of obesity appear to increase continuously with increasing weight, any attempt to distinguish between subgroups is necessarily arbitrary. It is helpful for treatment purposes, however, to divide the spectrum of obese states into the categories shown in the Appendix.

Methods

Patients and Program Description

A total of 668 outpatients enrolled in the Center for Nutrition Research (CNR) Clinic between 1973 and 1977. Many came on their physicians' advice but most were self-referred. Our approach emphasizes patients' responsibility for their own achievements. The major components are nutrition education, behavior modification, and exercise. These are described in detail elsewhere.^{8,9}

Patients included in this report were those who spent at least one week on the protein sparing modified fast (PSMF).¹⁰ This group does not include 60 patients enrolled in the CNR who had contraindications to supplemental fasting. We considered the following to be contraindications for the fast: pregnancy, age under 17 or greater than 75 years, Type I diabetes mellitus, myocardial infarction within six months, severe psychiatric disturbance (requiring drug therapy beyond minor tranquilizers), and severe hepatic or renal disease. With the exception of 62 patients in research protocols, the PSMF was restricted to patients with moderate or more

severe obesity (≥ 130 per cent of ideal body weight). Almost all of the clinic population consisted of white, upper-middle class United States citizens. Other than a few patients whose diet was initiated in hospital because they were on higher doses of insulin or anti-hypertensive agents, all care was provided in an outpatient setting.

The initial stage of the program lasted approximately four weeks. In the first week, patients were asked to record their usual food intake and physical activities. Then they were placed on a 1,000 kcal balanced deficit diet (BDD) for three weeks and instructed to continue recording their food intake and activity. This record was reviewed with patients weekly. Initial medical evaluation included a medical history and physical examination by a physician, a complete blood count, blood chemistries, urinalysis, chest x-ray, electrocardiogram, and the Minnesota Multiphasic Personality Inventory.

If no contraindications had been noted during the initial weeks, patients were placed on the PSMF. This diet provides a daily intake of 1.5 gm of protein per kilogram of ideal body weight in the form of lean meat, fish, or fowl. Preweighed portions are divided over two to three meals per day. In addition, patients receive a supplement providing the RDA for all vitamins and essential minerals except calcium, magnesium and phosphorous, and 400 mg calcium. Patients were encouraged to drink a minimum of 1.5 L of fluid a day and to consume at least 5 gm of sodium chloride.

Weekly clinic visits were scheduled during which weight, blood pressure, and urine and breath ketone levels were monitored by a nurse. Patients then met with a counselor to review their progress, gain support, and set realistic goals for coping with specific food-related problems. The clinic counselors were individuals with training in psychology at the undergraduate or master's level who worked under the supervision of a clinical psychologist. Patients also had weekly educational lectures, discussions, or readings. Topics included nutrition, methods of behavior change, and exercise physiology.

When patients neared their target weight, a refeeding and maintenance program was initiated. This was prescribed as a 12-week program in which carbohydrate was gradually added until a balanced maintenance diet was established. During this period patients met weekly with their counselor where techniques for maintaining weight while coping with everyday food cues were discussed.

Information for this report was abstracted from the medical record of every patient treated with the PSMF for at

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TABLE 1—Patient Characteristics at Time of Enrollment

	All Patients	Women	Men
Number of patients	668	564	104
Age (yrs)	38 ± 11*	38	41
Entry Weight (lb)	216 ± 49	207	264
Entry Weight (kg)	98 ± 22	94	120
Height (cm)	165 ± 6	163	177
Ideal Body Weight (kg)	57 ± 7	55	69
Per Cent Excess Weight	71 ± 34	70	74
Body Mass Index	36 ± 7	35	38
Age of Obesity Onset	16 ± 12	16	16
Years of School	15 ± 2	15	16
% Who are Married (N = 319)	67	66	74
% Who had Obese Father (N = 122)	63	57	91
% Who had Obese Mother (N = 123)	73	71	82

*mean ± standard deviation.

least seven days during the years 1973–77. Data on physiological parameters (blood pressure and blood chemistries) and family history were obtained on half of the population, selected by choosing every other chart from an alphabetical file.

Definition of Variables

Most patients in our program participated in a maintenance phase following the PSMF. As a result, their final weight on completing the program was often different from the lowest weight reached while on the fast. The latter value is termed minimum weight and is reported along with the final weight measured in our program. Excess weight is based on the 1959 Metropolitan Life Insurance Company weight for height standard.⁴ Body frame was not taken into account, except in the extreme cases of a very small frame. The mid-point of the ideal weight for each height was selected as a reference point.

We also report an additional measure, *Feinstein's Weight Loss Index*, because it takes into account both height, weight, and the initial excess weight.^{11,12} This index is calculated as the per cent excess weight lost times (initial weight/ideal weight). Statistical comparisons between groups are based on the Student's t-test, Pearson product moment correlations, and step-wise multiple regression.

Results

Table 1 describes the characteristics of our patients on entry to the program.

Adherence to Program and Weight Loss Results

Table 2 shows measures of weight change from entry to the minimum weight in the program and to the final weight recorded. The minimum and final values shown in these Tables are all significantly different from entry values. Final weights indicated that the average patient had regained only 6.2 ± 12.1 lbs. during the refeeding/maintenance period. While weight loss averaged one-fifth of total body weight, it represented almost half of the patients' weight above ideal.

Each patient was classified as a success or failure according to different criteria to allow comparison with other weight loss studies. Table 3 shows the result of using differing criteria of weight loss success. Some criteria are easier for the heaviest patients to reach and some are more difficult. For example, 70 per cent of the heaviest half of our population had lost 40 lbs. at their minimum weight but only 25 per cent reached ≤ 130 per cent ideal body weight.

TABLE 2—Weight Loss Results

	Total (mean ± SD)	Women (mean)	Men (mean)
From Entry to Minimum Weight			
Weeks from entry to minimum weight	21.20 ± 11.80	20.6	22.19
Weeks on PSMF	17.42 ± 11.72	17.8	15.4
Kilograms lost	21.44 ± 13.27	20.5	26.7
% Excess body weight lost	56.54 ± 26.23	57	53
Weight reduction index	93.90 ± 41.75	94	92
From Entry to Final Weight			
Weeks in from entry to final weight	31.29 ± 21.95	32.1	26.7
Kilograms lost	18.60 ± 13.00	12.0	23.9
% Excess body weight lost	48.30 ± 25.86	48	48
Weight reduction index	80.69 ± 42.75	80	83

TABLE 3—Alternative Measures of Success for Short-term Weight Loss

	All	Women	Men
Entry to minimum weight			
N	668	564	104
% Patients losing 40 lbs	50	47	63
% Patients reaching ≤130% IBW	53	53	54
% Patients losing half excess weight	57	57	54
% Patients reaching Reduction Index of 60	76	77	76
Entry to final weight			
% Patients losing 40 lbs	42	38	60
% Patients losing ≤130% IBW	47	46	47
% Patients losing half excess weight	46	46	47
% Patients reaching Reduction Index of 60	66	64	73

Changes in Physiological Parameters

As shown in Table 4, systolic blood pressure fell an average of 13 mm Hg and diastolic blood pressure fell 8 mm Hg. Mean fasting blood sugar fell by 15 mg/dl and serum triglycerides by 37 mg/dl. All of these changes are highly significant by paired t-test ($p < .0001$).

Serum cholesterol changes were variable, and sex-related. Despite an increase in mean cholesterol for women, the per cent of women who had a cholesterol level ≥ 200 mg/dl fell from 64 per cent at entry to the program to 40 per cent at the final measurement. While 28 per cent of women had a serum cholesterol of ≥ 250 at entry, only 23 per cent did at the final measurement. Average uric acid levels rose slightly, by 0.4 mg/dl.

Predictors for Weight Loss

Other than measures of excess weight, few of the variables available to describe patient characteristics on entry to the clinic were correlated with eventual weight loss. The per cent excess weight at entry was strongly correlated with both pounds lost at minimum ($r = .58$) and per cent of excess weight lost at minimum ($r = .30$). Although age at entry and reported age of onset of obesity showed small, significant correlations with weight loss, these relationships did not persist in a multiple regression using the maximum R-square improvement technique in which weight at entry was included. Marital status, years of education, family history of obesity, and entry blood pressure, triglycerides, and cholesterol were not correlated with weight loss success.

Table 5 illustrates the strong relationship between the time patients remained on the PSMF and their weight loss. Time on the PSMF is also strongly related to the degree of patient weight problem at entry.

TABLE 4—Changes in Physiological Parameters from Entry to Final Assessment

	N	All Patients	Female	Male
Systolic Blood Pressure (mm/Hg)				
Entry	335	135	133	144
Entry—final	334	12.99	12.76	14.34
95% confidence intervals on change value		(11.02, 14.96)	(10.65, 14.87)	(9.12, 19.49)
Diastolic Blood Pressure (mm/Hg)				
Entry	335	87	86	93
Entry—final	334	8.37	7.87	11.2
95% confidence intervals on change value		(7.07, 9.67)	(6.53, 9.21)	(7.21, 15.19)
Blood sugar (mg/dl)				
Entry	296	97	97	97
Entry—final	170	14.77	15.07	12.73
95% confidence intervals on change value		(11.96, 17.58)	(8.87, 21.27)	(4.43, 21.03)
Triglycerides (mg/dl)				
Entry	301	133	127	170
Entry—final	154	36.75	28.24	101.06
95% confidence intervals on change value		(31.04, 42.45)	(17.63, 38.85)	(62.47, 139.65)
Cholesterol (mg/dl)				
Entry	327	225	225	225
Entry—final	181	-6.53*	-10.85*	23.13
95% confidence intervals on change value		(-11.04, 2.02)	(-20.44, -1.26)	(4.69, 41.57)
Uric Acid (mg/dl)				
Entry	327	5.9	5.6	7.6
Entry—final	180	-0.40*	-0.50*	-0.30*
95% confidence intervals on change value		(-0.82, 0.02)	(-0.73, -0.27)	(-0.71, 0.11)

*negative values indicate increase in parameter from entry to final measurement.

TABLE 5—Entry Characteristics, Outcomes, and Compliance with PSMF

	Time Patient Remained on PSMF (weeks)			
	0-6	7-12	13-24	≥25
Entry Characteristics				
N	119	156	227	166
Age	35 ± 11	38 ± 11	39 ± 11	40 ± 10
Age of obesity onset	17 ± 12	17 ± 12	16 ± 12	13 ± 12
Weight (kg)	91 ± 23	93 ± 21	97 ± 21	109 ± 22
Weight (lb)	199 ± 51	205 ± 45	214 ± 46	239 ± 48
Outcomes				
Kilograms lost	9.39 ± 6.98	14.70 ± 5.10	22.75 ± 9.37	34.62 ± 14.41
Pounds lost	20.66 ± 15.37	32.35 ± 11.23	50.05 ± 20.62	76.17 ± 31.70
% Excess body weight lost	35 ± 23	51 ± 28	62 ± 24	69 ± 19
Weight Reduction Index	51 ± 28	77 ± 30	102 ± 31	129 ± 37

Side Effects and Mortality

The principal symptom experienced by patients on the PSMF was mild postural lightheadedness occurring in a minority of patients in the first two weeks. This was usually relieved by increasing salt intake. All patients noticed a decrease in the quantity and frequency of bowel movements but only a few required laxative therapy. A small number of patients experienced generalized hair loss after many weeks on the fast. This transient phenomenon has been described elsewhere as "telogen effluvium."¹³ There were no deaths among patients while undergoing the PSMF. We are aware of five deaths in the patients described in this report, all of which occurred at least one year after leaving the program. This mortality rate is consistent with that expected in this population.

Other weight loss studies have reported emotional disturbances in a significant number of obese patients, including onset or intensification of depression and anxiety.^{14,15} Very few of these symptoms were observed in our program. Most patients felt well on the PSMF and were encouraged by their

ability to lose weight. Emotional problems may occur once the patient is off the diet struggling to maintain weight loss: feelings of failure and frustration were noted in patients who were unsuccessful in maintaining the weight loss at the maintenance stage.

Discussion

Our results are better than those seen in programs using primarily behavior therapy¹² and compare favorably with 14 other major studies using very low calorie diets.¹⁶⁻²⁹ Since all of the patients described here were offered the same multidisciplinary program of diet, exercise, behavior modification, and nutrition education, it is not possible to assess the relative contribution of each component to the program's success.

In many of the very low calorie diet studies cited above, patients were treated with formula diets containing various combinations of milk or egg protein and carbohydrates. No added carbohydrate is provided on the PSMF, in contrast to most of the studies cited above. We believe that the pronounced ketosis seen when carbohydrate is absent enhances

the anorectic effects of the diet. Although early empirical evidence on this effect was conflicting,^{3,30-31} a recent randomized trial found that patients on a PSMF reported significantly less hunger and preoccupation with eating when compared to patients on a formula diet with carbohydrate included.³²

Carbohydrate apparently does not improve protein sparing in very low calorie diets.³³⁻³⁵ Contaldo has shown that obese patients on a 180-Kcal diet containing 40 grams of protein experienced significantly better nitrogen balance than patients on an isocaloric diet in which 26 grams of carbohydrate replaced some of the protein.³⁶

On the other hand, two studies using a small number of subjects were unable to show a difference in protein sparing between protein and protein plus carbohydrate,^{37,38} but both studies had a number of methodologic problems.³⁹

There is another theoretical advantage to omitting carbohydrate from a very low calorie diet. If a diet contains the minimum amount of protein needed to prevent loss of lean body mass, addition of carbohydrate adds calories and will therefore decrease the rate of weight loss.

In a recent randomized trial in 17 healthy obese women, a diet containing 1.5 gm protein/kg ideal body weight was found to result in significantly better protein sparing than an isocaloric diet providing only .8 gm protein/kg ideal body weight.⁴⁰ Patients lost weight at the same rate on the two diets, but since there was less nitrogen loss on the diet without carbohydrate, it can be assumed that more fat loss occurred than on the diet where carbohydrate replaced some of the protein.

Reports of weight loss typically show that absolute weight loss and per cent excess are correlated with starting weight.^{11,24,25,29} The magnitude of our patients' average systolic and diastolic blood pressure reductions are consistent with the 7 mmHg per 10 per cent reduction of relative weight noted in the Framingham Study.⁴¹ The hypotensive effect of weight loss has been shown to be due to factors other than changes in sodium balance. Hypothesized mechanisms include changes in sympathomimetic hormone activity, adjustments in the renin-angiotensin system, and reduction and redistribution of blood volume.^{16,42,43} The potential efficacy of this approach is supported by our finding that 108 of our 160 patients who initially had diastolic blood pressures >90 mmHg were normotensive following weight loss.

Our finding that serum triglycerides fell significantly in both men and women is also consistent with those of many previous studies.^{9,20} Clinical studies of weight loss programs have reported variable effects on cholesterol and high density lipoprotein.^{2,44,45} Observed changes in serum cholesterol with weight loss may have been due to the fact that cholesterol rises transiently in some individuals following about 40 lbs of weight loss.

Serum uric acid is known to rise in individuals on ketogenic regimens providing less than 900 calories per day. Uric acid also follows a biphasic course on the PSMF, rising slightly over the first 6-8 weeks and then falling during maintenance of a new, lower weight. Attacks of acute gouty arthritis, however, occurred in less than 1 per cent of our subjects.

For most patients with moderate or more severe obesity (≥ 130 per cent ideal body weight), very low calorie diets provide a safe opportunity to lose a large fraction of their excess weight. Unfortunately, this weight loss does not always constitute a cure because many patients eventually gain back much or all of the lost weight.²

The fact that only a minority of the patients maintain long-term weight reduction should not be an excuse for therapeutic nihilism. All obese patients deserve an opportunity to achieve long-term weight reduction. Even for those who fail to maintain their losses, weight regain is often not immediate. It is not known to what extent a few years of weight reduction provides some reduction in cardiovascular risk. Other approaches to control of cardiovascular risk are also subject to long-term compliance problems. For example, at five year follow-up in the Hypertension Detection and Follow-up Program, 20-36 per cent of patients in the Stepped Care group (treatment arm) had diastolic blood pressures above the target level.⁴⁶

Relatively short duration of weight reduction may confer other benefits. For example, decreases in medications for hypertension and diabetes could reduce side effects, drug costs, and physician visits for a few months or years. Symptoms of breathlessness and osteoarthritis are likely to be ameliorated when weight is down. Moreover, patients who undergo major elective surgical procedures during the time their weight is reduced could have lower risk of complications.⁴⁷⁻⁴⁹

Weight loss followed by rapid regain, on the other hand, may be harmful. We have observed, along with others, that patients seem to have a more difficult time on VLCD programs which follow previous weight loss and regain [Kelly Brownell, PhD, personal communication]. Until more is known about the benefits and risks of transient weight reduction, very low calorie diets should only be conducted under the supervision of experienced clinicians and in conjunction with behavior modification programs to maximize the chance of long-term weight maintenance.

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APPENDIX

Classification, Incidence, and Risk of Obesity

Category	Per Cent Relative Weight	Incidence per 1000 ^a		Relative Risk of Mortality
		Male	Female	
Normal	100-110	263	184	1
Mild Overweight	110-120	181	127	1.16 ^b
Mild Obesity	120-130	81	106	1.28 ^b
Moderate Obesity	130-160	53	119	1.46 ^b
Severe Obesity	160-200	7	34	3-5 ^b
Morbid Obesity	200-250		8	6-13 ^{c,d}
Super-morbid Obesity	>250			>15 ^d

a) NCHS Study.⁵⁰

b) Lew and Garfinkel's American Cancer Society Study.³

c) Dublin and Marks, Metropolitan Life Study.⁵¹

d) Drenick, Bales, Seltzer Study.⁵²